

*Response Under 37 CFR § 1.116 \* -- Expedited Procedure -- Examining Group 1615  
Docket No.: 1408.017  
Serial Number: 09/882,382*

## AMENDMENT

This listing of claims will replace all prior versions and listings of claims in the application.

### Listing of Claims

1. **(Currently Amended)** A composition for use in manufacturing an adhesive layer for transdermal preparation having an adhesive layer-said composition comprising a non-aqueous solvent, a drug to be delivered through skin and an acrylic polymer a solution-type acrylic adhesive, wherein the drug is hydrophilic or in a salt form and the solution-type acrylic adhesive acrylic polymer has an acrylic backbone and a poly (ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain.
2. **(Currently Amended)** The transdermal-preparation-composition according to claim 1, further comprising at least one additional component chosen from a solubilizer and a skin permeation enhancer.
3. **(Currently Amended)** The transdermal-preparation composition according to claim 1, wherein the amount of drug in the preparation is in a range of 1-50% by weight, based on the total weight of the adhesive layer.
4. **(Currently Amended)** The transdermal-preparation-composition according to claim 1, wherein the molecular weight of the poly (ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether in the acrylic-adhesive-acrylic polymer is in the range of 0.01-50% by weight based on the total weight of the acrylic-adhesiveacrylic polymer.
5. **(Currently Amended)** The transdermal-preparation-composition according to claim 4, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 400-5000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether in the acrylic-adhesiveacrylic polymer is in a range of 0.05-30 % by weight based on the total weight of the acrylic-adhesiveacrylic polymer.

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6. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 1, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, hydrobromide, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phosphate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

7. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 2, wherein the solubilizer comprises at least one component selected from a group consisting of ethanol, isopropanol, poly(ethylene glycol), ethoxydiglycol, - propylene glycol, glycerin and dimethylsulfoxide, and wherein the amount of solubilizer in the adhesive layer is in a range of 0.5-50% by weight based on the total weight of the adhesive layer.

8. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 2, wherein the skin permeation enhancer comprises at least one component selected from a group consisting of higher fatty acids; higher alcohols; higher fatty acid esters; fatty acid esters; fatty acid ethers of poly(ethylene glycol); fatty acid esters of poly(ethylene glycol); fatty acid ethers of propylene glycol; fatty acid esters of propylene glycol; sorbitan fatty acid esters; poly(ethylene glycol) sorbitan fatty acid esters; terpenes; sulfoxides; pyrrolidones; amides; and *N*-hydroxy methyl lactate, sorbitol, urea, squalene, olive oil, mineral oil and its derivative, and wherein the amount of skin permeation enhancer in the adhesive layer is in a range of 0.5-50% by weight based on the total weight of the adhesive layer.

9. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 8, wherein the skin permeation enhancer comprises at least one component selected from a group consisting of lauric acid, oleic acid, lauryl alcohol, oleyl alcohol, glycerol monolaurate, glycerol monooleate, polyoxyethylene(2) lauryl ether, polyoxyethylene(2) oleyl ether, propylene glycol monolaurate, propylene glycol monooleate, sorbitan monolaurate, sorbitan monooleate, lauryl diethanolamide, *N*-methyl-2-pyrrolidone and isopropyl myristate.

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10. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 7, wherein the amount of the solubilizer and of the skin permeation enhancer in the adhesive layer are each in a range of 1-30% by weight, based on the total weight of the adhesive layer.

11. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 2, wherein the amount of drug is in a range of 1-50% by weight, based on the total weight of the adhesive layer.

12. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 2, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in the range of 0.01-50% by weight based on the total weight of the acrylic adhesive acrylic polymer.

13 **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 2, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, hydrobromide, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phosphate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

14. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 8, wherein the amount of the solubilizer and of the skin permeation enhancer in the adhesive layer are each in a range of 1-30% by weight, based on the total weight of the adhesive layer.

15. **(Currently Amended)** The ~~transdermal-preparation~~composition according to claim 9, wherein the amount of the solubilizer and of the skin permeation enhancer in the

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adhesive layer are each in a range of 1-30% by weight, based on the total weight of the adhesive layer.

16. **(Canceled)** ~~An adhesive for use in the transdermal delivery of a hydrophilic or salt form drug, the adhesive comprising an acrylic polymer including a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.~~

17. **(Canceled)** ~~A pharmaceutical dosage form for transdermal delivery of a hydrophilic or salt form drug, the dosage form comprising an amount of the drug and an acrylic polymer adhesive, wherein the acrylic polymer has a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.~~

18. **(New)** A method for manufacturing a transdermal preparation, said method comprising

combining a non-aqueous polymer solution with a drug to be delivered through skin, wherein the drug is hydrophilic or in a salt form and the non-aqueous polymer solution comprises a polymer having an acrylic backbone and a poly (ethylene oxide) or poly (ethylene oxide) monomethyl ether side chain; and

applying the resulting solution to a substrate to form a transdermal preparation having an adhesive layer comprising the drug and the polymer.